

Application No.: 10/593372
Filing Date: January 12, 2007

REMARKS

Claims 99-102 and 104-107 have been amended. New claims 108-118 are added. Claim 103 has been canceled. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 103 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 103 has been canceled. Accordingly, this ground is moot.

Rejection under 35 U.S.C. § 103(a)

Claims 99-107 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Selvais, et al. (J. Cardiac Failure 6: 201: 2000), Hülsmann, et al. (J. Am. Coll. Cardiol 32: 1695, 1998), Rousseau, et al. (Circulation 108 (17 Suppl): IV-556, 2003), Berger et al. (J. Heart Lung Transplant. 22: 1037, 2003), and Sabatine, et al. (Circulation 105: 1760: 2002).

Applicants have amended the claims to “A method of predicting survival outcome of an individual suffering from ~~severe-mild~~ congestive heart failure”. The method depends upon the combination of a first marker N-proANP (1-98) in combination with a second marker can be BNP, N-proBNP or Big ET-1 (1-38) as described in Figure 20 (sheets 23 & 24) of the specification. Support for the amendment is found in original claims 67, 69 and 79, and Figure 20 of the specification. Claim 67 refers to “proBNP or immunologically detectable fragments” which are further defined in the specification at paragraphs 0073-0078.

Regarding the cutoff values of amended claim 99, support for the range 1.7-3.3 fold a normal level for N-proANP is found in original claim 69. Support for the cutoff level of BNP or N-proBNP of about 1.3-7 fold a normal level for BNP or N-proBNP is found in original claim 69. Support for the cutoff level of Big ET-1 (1-38) of about 1.6-2.4 fold a normal level is found in original claim 95.

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For the dependent claims, support for the recitation of a cutoff level of 2.6 to 7 for BNP in amended claim 100 is found in original claim 80. Support for 2 fold a normal level for Big ET-1 (1-38) in amended claim 101 is found in original claim 96. Support for 1.9 fold a normal level for N-proANP(1-98) in amended claim 102 is found in original claim 72. Support for the range of 4.4-5.7 fold a normal level for BNP as recited in new claim 116 is found in original claim 81. Support for the range of 1.3-1.8 fold the normal level for N-proBNP in new claim 117 is found in original claim 83.

Support for claims 104-115 is found in Figure 20 (sheets 23 & 24). Claim 118 further limits claim 99.

The claims as amended are believed to be patentable over the cited references taken as a whole. The references taken as a whole relate primarily to severe CHF, not to mild CHF as now claimed. Of the five cited references, only Berger, et al. specifically study mild CHF. However, there is nothing in Berger, et al. which would lead one of ordinary skill in the art to combine proANP (1-98) with either proBNP or Big (ET-1).

The amendment is also responsive to the Examiner's comment in the Office Action of 12/21/10 that the Declaration of Gerhard Hawa focuses on mild congestive heart failure while the claims are limited to severe congestive heart failure. Accordingly, in order to expedite prosecution, the present claims are amended and are commensurate in scope with the evidence presented in the Declaration of Gerhard Hawa, presented with the previous response filed November 9, 2010. That is the present claims are limited to mild congestive heart failure. As noted particularly in item 4 of the Declaration, "Differences between the outcomes of measuring BigET-1 and ET-1 are especially pronounced when applied to patients with mild CHF (NYHA I-II): Tables 2 and 3; Figs 3 and 4". The predictive value of Big ET-1 (1-38) for survival estimate in mild CHF patients was unexpected and could not have been predicted from the cited references.

In view of the claim amendments, arguments and previously presented Declaration of Gerhard Hawa, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

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No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 21, 2011

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